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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,382	04/12/2004	Christian Georg	P04,0140	2858

7590
SCHIFF HARDIN LLP
Patent Department
6600 Sears Tower
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Chicago, IL 60606

EXAMINER

LAMPRECHT, JOEL

ART UNIT	PAPER NUMBER
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3737

MAIL DATE	DELIVERY MODE
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04/28/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/822,382	Applicant(s) GEORG ET AL.	
	Examiner JOEL M. LAMPRECHT	Art Unit 3737	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 January 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-4, 6, 7-10, and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche et al (US 2001/0034480 A1) in view of Lang et al (US 6,811,310 B2). Rasche et al disclose a method for detecting and localizing objects using single x-ray projection images (0010), and multiple projection images from different directions (or times, 0011) with a priori knowledge to ascertain geometric data relating to a medical patient, including implants (0025) with x-ray detectable markers (0017-0025). The distribution of detected elements is performed with digital image

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processing (0008-0015), and implants are disclosed with detectable points thereon (0031-0033, 0014).

Rasche et al do not disclose a probability calculation for determining if a first and second distribution are from the same distribution, or the use of calibration techniques to acquire images. Attention is then directed to the secondary reference by Lang et al which discloses a plurality of image analysis methods and also calibration methods for forming calibrated image exposures for comparison (Col 4 Line 45-Col 5 Line 35, Col 8 Line 50-Col 10 Line 68). Lang et al specifically discloses statistical methods and aggregate algorithms for point-based location and tracking of x-rays ((see probability of similar distributions) From Col 15 Line 55-Col 17 Line 55, Col 18 Line 13-Col 20 Line 5, and Col 27 Line 45-65 for display on Col 18 Line 1-11). It would have been obvious to one of ordinary skill in the art at the time of the invention to have employed the data-analysis, and calibration methods of Lang et al in the x-ray projection methods of Rasche et al for the purpose of providing the most accurate and detailed analysis of positional and diagnostic data to assess implant or other bone factors of a patient.

Claims 5 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rasche et al (US 2001/0034480 A1) in view of Lang et al (US 6,811,310 B2) as applied to claims 1 and 7 above and in further view of Allen (4,991,579). Rasche et al in view of Lang et al disclose what is listed above, but fail to mention the use of spheres as markers which can be disposed in at least one bone bordering a prosthesis. Attention is then directed to the teaching reference to Allen which discloses such spheres specifically for the purpose of providing capacity for repeated image acquisition for

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consistency (Col 1-2 for motivation, Figure 1-4 for implants and coordinates, Col 4 Line 55-Col 5 35 for implant insertion). It would have been obvious to one of ordinary skill in the art to have utilized the implants of Allen with the methods of Rasche et al and Lang et al as they provide a consistently sized reference for image processing (See Lang et al for further motivations about consistent geometry).

Response to Arguments

Applicant's arguments filed 1/21/09 have been fully considered but they are not persuasive. With regard to the first argument that Rasche et al lacks motivation to combine with the reference to Lang et al. Examiner respectfully disagrees and offers the following explanation. Rasche et al pertains to localization of objects during or after an interventional procedure through acquisition of projection images with x-ray detectable markers thereupon in order to provide data regarding the distribution of said markers with respect to the area of interest, namely the coordinate system of the procedure. The projection images provide the exact representation of the markers, which can be situated both in bones or implants (0025) so that spatial positions can be determined at any time.

Lang et al provide an additional step of analysis of x-ray images and data-points derived therefrom. Bone structures, including those with implants imposed thereupon, are described for statistical analysis to determine anatomical positioning (Col 9 Line 55-Col 10 Line 55), and to diagnose implant failure, or a shift in the anatomy of a patient via an image analysis method which is capable of building and comparing data over time (Col 13 Line 19-64, Col 15 Line 55-Col 16 Line 58, Col 18 Line 23-41, Col 19 Line 29-

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49, All leading to Col 27 Line 45-55 and Col 28 Line 65-Col 31 Line 25 describing the analysis leading to diagnosis) for a patient in order to provide this diagnosis based on thresholds and automatic calculations from the data being analyzed.

Rasche cites in background that position and orientation of an object is desired to be localized accurately and also cites that the inclusion of a radiological apparatus for diagnosis is also desirable (0026). Therefore it would have been obvious to one of ordinary skill in the art at the time of the invention would to have utilized a diagnostic apparatus for analysis and image processing (0032) alongside the acquisition/marketing techniques of Rasche et al for the purpose of allowing for accurate and reliable assessment of bone structure over time from x-ray images (Abstract, Lang et al).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL M. LAMPRECHT whose telephone number is (571)272-3250. The examiner can normally be reached on 8:30-5:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/BRIAN CASLER/
Supervisory Patent Examiner, Art
Unit 3737

JML